

K012711 DISPOSABLE POWDER FREE VINYL PATIENT EXAMINATION GLOVESSep 18, 2001
35 days to decisionK012711 · Product code: LYZ · General Hospital
Source: <https://www.510kdatabase.net/k012711/>**SUBMISSION DETAILS**

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|-----------------------|---------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Vinyl Patient Examination Glove (LYZ) |
| Date received | Aug 14, 2001 |
| Decision date | Sep 18, 2001 |
| Days to decision | 35 days |
| Third-party review | No |
| Summary / Statement | Statement |

APPLICANT

| | |
|----------------|--|
| Company | Shijiazhuang Brilliance Plastic Co., Ltd. |
| Location | North Billerica, MA, US |
| Contact | HUAN CHUNG LI |
| 510(k) history | 2 submissions · 2 cleared · 2001-2001 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k012711/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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